

WRAMC Vaccine Information Sheet for Lyme Disease

ABOUT THE DISEASE:

Lyme disease is an infection resulting from the bite of certain types of ticks. This infection can cause disease in patients of all ages and can result, for some patients, in a chronic illness affecting the joints, nervous system and heart. The disease can be treated with antibiotics and this treatment prevents the chronic disease. Unfortunately, one infection does NOT protect a person from future infections. Only a certain kind of tick (deer ticks) can carry this disease and infection is possible only in certain areas of the country. Lyme infections can be prevented through specific measures to assure avoidance of tick bites and/or early removal of ticks since infection requires that the tick be in place for more than 24 hours.

Acute Infection can present as:	Chronic or Late Onset Disease can result in:
<ul style="list-style-type: none">• A red spotty rash with some bulls-eye appearing patches• Illness with fever, fatigue, headache, sore muscles and joints Some patients have no clinical symptoms but become infected after a tick bite: <ul style="list-style-type: none">• silent infection	<ul style="list-style-type: none">• Rashes and/or Illness involving• arthritis• fevers, muscle aches and fatigue• palpitations or irregular heart beat Long term disability or illness (rarely fatal).

ABOUT THE VACCINE

Benefits of the Vaccine

Based on clinical studies before licensing of this new vaccine, receiving the full course of immunization with 3 doses in the first year (at 0, 1 and 12 months) and yearly booster shots results in approximately 80% protection from infection. Markedly reduced vaccine effectiveness occurs when less than 3 doses are administered in the first year. The use of this vaccine does NOT protect against other tick borne disease and does NOT eliminate the need for tick bite avoidance, evaluation or precautions following exposure. There is a strong possibility that yearly booster shots will be required for several years in order to maintain protection.

Who should get the Lyme vaccine?

There are no national recommendations requiring this vaccine for any group of patients including active duty military personnel. The Advisory Council for Immunization Practices (ACIP) suggests that the decision to vaccinate should be based on a high risk of exposure and the inability to effectively practice tick bite precautions. Since there are risks with any vaccine and this vaccine has a number of side effects associated with it (see below), a careful discussion with the primary care provider regarding the benefits versus risks of vaccination should be considered before the vaccine series is started. The vaccine is only approved for ages 15 to 70 and is primarily recommended for persons who live, work or play in high risk environments.

NOTE: High risk US States include Connecticut, Delaware, **Maryland**, New Jersey, New York, Pennsylvania, Rhode Island, and Wisconsin; **Moderate risk US States** include Maine, Massachusetts, Minnesota, New Hampshire, Vermont; **Low risk US States** include Alabama, Arizona, Arkansas, California, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Nevada, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia.

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Contraindications for the Lyme Vaccine (LYMErix™)

At this point in the history of the vaccine experience, the National Capital Region Immunization Working Group suggests that the following patient conditions should result in exclusion from receiving the vaccine:

- *Chronic Lyme disease or Prior Lyme arthritis*
- *Prior Lyme associated neurologic disease*
- *Pregnancy*
- *Age less than 15 years or older than 70 years*
- *Any history of autoimmune disease*

There is a concern by some physician groups that this vaccine may, rarely, cause chronic arthritis in certain types of patients with a genetic marker known as HLA-DR4.

Because the safety of rOspA vaccines administered during pregnancy has not been established, vaccination of women who are known to be pregnant is not recommended. A **vaccine pregnancy registry** has been established by SmithKline Beecham Pharmaceuticals. In the event that a pregnant woman is vaccinated, health-care providers are encouraged to register this vaccination by calling 1-800-366-8900, ext. 5231.

Adverse Reactions to LYMErix™: A More Detailed Review

Although the Lyme vaccine has been approved by the Food and Drug Administration as safe and effective, a significant number of side effects have been reported by those individuals who received the vaccine and its placebo control (containing everything in the actual vaccine except the Lyme protein). Local pain, tenderness or both occurred in up to 85% of subjects. Redness and swelling at the injection site was described in 10-15%. Resolving in generally less than a week, generalized **reactions** were reported in up to 40% of patients and included the following: joint tenderness and stiffness, fatigue, rash, headache and/or fever less than 102.2°F. There is always a rare risk for a potentially life threatening allergic reaction. **Patients interested in receiving the vaccine should carefully review the detailed educational material and discuss their benefit versus risk in relation to a decision for or against vaccination.**

What to do if there is a serious reaction:

- K Call a doctor or get the person to a doctor right away.
- K Write down what happened and the date and time it happened.
- K Ask your doctor, nurse or health department to file a Vaccine Adverse Report form or call (800) 822-7967 (toll-free).
- K This vaccine is NOT covered under the National Vaccine Injury Compensation Program for persons thought to be injured by this vaccine.
- K If you want to learn more about the vaccine and its side effects, ask your doctor, the staff of your immunization clinic or your pharmacist for a copy of the vaccine package insert.
- K Additional information from the national reviewing organization (ACIP) is available at the following web-site: <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4807al.htm>
- K *Physicians and patients should register in the manufacturer's confidential reminder system (LYMEtrax™ Patient Reminder Program, Fax 1-800-386-6144) to assure vaccine dosing compliance.*